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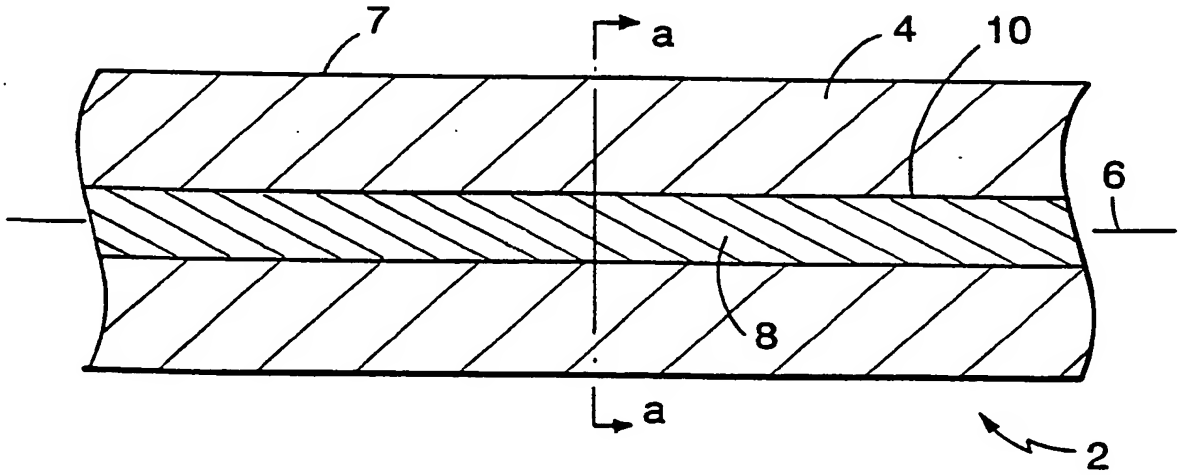

(57) Abstract

A medical device (2) and method for treatment in which the device has a portion for use within the body that exhibits enhanced properties such as radiopacity for viewing by x-ray fluoroscopy. The portion includes an extended metal outer member (4) having, e.g., a predetermined density and an exposed outer surface and a core (8), including a metal having, e.g., a density greater than the outer member to enhance radiopacity, substantially enclosed by the outer member (4).

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MEDICAL WIRE

Field of the Invention

This invention relates to metal medical components to be used inside the body, such as medical wires used, for example, in guidewires, filters, and other medical devices.

Background of the Invention

Noninvasive medical procedures reduce the risk of surgery by introducing medical devices to a body cavity through small incisions or body orifices. The devices are carefully designed so that they may be controlled from the proximal end remaining outside the body to carry out the required treatment at the desired location inside the body. In one of the most common noninvasive techniques, angiography, a device, such as a guidewire, balloon angioplasty catheter or the like, is advanced and torqued at its proximal end to steer the device through a blood vessel to the position of an occlusion at which point a medical procedure such as balloon angioplasty and/or positioning of an endoprosthesis is carried out.

Typically, X-ray fluoroscopy is used to view the medical device within the body cavity to monitor placement and operation. The device may also be viewed by X-ray film after placement. To use these techniques, particularly with small devices which may be difficult to view, the medical device must include some radiopaque material, more dense than the surrounding tissue, to provide sufficient contrast on an X-ray image. A highly dense, and therefore particularly radiopaque, metal is usually incorporated with the portion of the medical device used inside the body for this purpose.

Summary of the Invention

In interventional medicine, wires can be used for a variety of purposes such as tracking, stenting,

filtering, conducting (electric current, ultrasound energy, etc.) and marking. Desirable attributes of these wires vary with application, but include properties such as stiffness, tensile strength, elasticity, radiopacity, weldability, flexural life, conductivity, etc. These properties are hard to find in single-material constructions. It is possible to achieve optimum properties by creating a multiple material coaxial construction. In medical wires, for example, it can be very desirable to have high radiopacity along with elasticity and strength. This may be accomplished by combining a radiopaque material with an elastic material. Although it is possible to put either material on the inside or outside, it would be preferable to put the dense radiopaque material (e.g., tantalum) on the inside (core) since dense materials are generally less elastic and the elastic material (e.g., titanium or nickel-titanium alloy) on the outside (clad). The clad or "skin" of the wire will undergo more deformation in bending than the core, so the elastic component is best positioned at the skin. In another medical application, it is desirable to have an elastic core (nitinol) for conducting axial vibrations (sonic or ultrasonic) and a thin stiff cladding (stainless steel) in order to minimize traverse vibrations which result in loss of energy.

An aspect of the invention is a metal medical device with at least a portion to be used within the body with properties that can be tailored to a particular application. The portion is formed of preferably two or more dissimilar metals joined together to form a unitary member. Typically, each metal contributes a desirable property to the device which is not substantially impaired by the presence of the other metal. In particularly preferred devices, one metal provides

enhanced radiopacity. In these embodiments, the medical device comprises a metal outer member having a predetermined density and an exposed outer surface and a core including a metal having a density greater than the outer member to enhance radiopacity. The core is secured within and substantially enclosed by the outer member. Preferably, the medical component is in the form of a wire configured such that the mechanical properties, for example, the elastic properties, of the metal forming the outer member are affected by the core to a desired degree so that the wire has a desired overall performance suitable for its intended use. Preferably, the mechanical properties of the outer longitudinal member dominate the properties of the wire yet the radiopacity is substantially enhanced by the denser core. The invention also allows increased radiopacity of a metal medical device without adversely affecting and in some cases improving other important properties such as the biocompatibility, size or other performance characteristics. These performance advantages can be realized by proper selection of the material of the outer member and core, their relative size, and geometrical configuration. The performance characteristics of the component may be dictated by the medical device into which the radiopaque medical component is to be incorporated.

The term "metal" as used herein includes electropositive chemical elements characterized by ductility, malleability, luster, and conductivity of heat and electricity, which can replace the hydrogen of an acid and forms bases with the hydroxyl radical and including mixtures including these elements and alloys. Many examples are given below.

In one aspect, the invention features a medical device having at least a portion for use within the body.

The portion includes an extended metal outer member having an exposed outer surface and a core within the outer member formed of a metal different than the metal of the outer member. The core is secured within and substantially enclosed by the outer member.

Various preferred embodiments may include one or more of the following features. The extended metal outer member is comprised of a metal of predetermined density and the core is comprised of a metal having a density substantially greater than the outer member to enhance radiopacity of the device. The portion is in the form of a medical wire, wherein the metal outer member is a longitudinal member and the radiopaque core is positioned along the axis of the longitudinal member. The radiopaque core has a density of about 9.9 g/cc or greater. The core is selected from the group consisting of tungsten, tantalum, rhenium, iridium, silver, gold, bismuth, platinum and alloys thereof. The core has a modulus of elasticity of about 550 GPa or less. The core has a modulus of elasticity of about 200 GPa or less. The outer member is selected from the group consisting of superelastic alloys, precursor alloys of superelastic alloys, stainless steel, and titanium and its alloys.

The superelastical alloy is nitinol. The core is about 1 to 40% of the cross-sectional dimension of the component. The core is about 25% or more of the cross-sectional dimension of the component. The core is about 28% or less of the cross-sectional dimension of the component. The cross-sectional dimension of the component is less than about 0.025 inch. The outer member has a cross-section of about 0.0045 to 0.008 inch and the core member has a cross-section of about 0.0014 to 0.00195 inch inner diameter. The core is a solid metallic member. The outer member has portions of varying dimension. The outer member has a taper portion.

The core has a constant inner dimension in portions corresponding to the varying outer dimension of the outer member. The portion is in the form of a medical guidewire. The portion is in the form of elastic leg members of a vascular filter. The outer member and core are of circular cross-sectional configuration. The portion is in the form of an ultrasonic probe. The probe is an elastic probe having a titanium core and nitinol outer member. The probe and core are constructed of materials of substantially different acoustic impedance. The acoustic energy is provided by axial excitation.

In another aspect, the invention features a medical wire device having at least a portion for use within the body. The portion includes an extended longitudinal metal outer member having a predetermined density and an exposed outer surface and a continuous solid core positioned along the axis of the outer member including a metal having a density of about 9.9 g/cc or greater and greater than the density of the outer member for enhancing radiopacity of the wire. The core is secured within and substantially enclosed by the outer member and is about 10 to 50% of the cross-sectional dimension of the portion for use within the body.

In various preferred embodiments, the core material is tantalum, the outer material is nitinol, and the cross sectional dimension of the portion is about 0.025 inch or less. The outer member has a cross-section of about 0.0045 to 0.008 inch and the core member has a cross-section of about 0.0014 to 0.00195 inch inner diameter. The wire is in the form of a guidewire. The outer member has portions of varying dimension such as a taper portion. The core has a constant inner dimension in portions corresponding to the varying outer dimension of the outer member. The cross-sectional dimension of the portion is about 0.035 to 0.037 inch. The core is

about 0.005 inch in diameter. The component is in the form of elastic leg members of a vascular filter.

In another aspect, the invention features a method for medical treatment by providing a medical device for performing a desired treatment, incorporating on at least a portion of the device a radiopaque medical component, formed of a metal outer member having a predetermined density and exposed outer surface and a core including a metal having a density substantially greater than the outer member to enhance radiopacity, the core being secured within and substantially enclosed by the outer member, and introducing the portion including the radiopaque medical component into the body, and observing the medical component by x-ray fluoroscopy.

In various preferred embodiments, the medical device is a guidewire and the medical component is a portion of the guidewire, the method further including steering the guidewire through the body from the proximal end. The medical device is a vascular filter.

In another aspect, the invention features a medical device capable of placement or manipulation in the body by means external of the body under guidance of a fluoroscope. The device is formed at least in part of an elongated wire-form metal member adapted to be subjected to elastic deformation to enable the device to be forced into a characteristic deformed configuration during a stage of use and to elastically self-recover from the deformation when deformation forces are relieved. The wire-form metal member is formed of a core of a first metal of a first selected thickness and an intimately surrounding sheath of a second selected metal of a second thickness, the first metal being a high density metal that demonstrates characteristic relatively high radiopacity and the second metal being a lower density metal having substantially more elasticity than

the first metal, the combined effect of the selected thicknesses of the first and second metals in the wire-form member serving to enhance the radio-opacity of the wire-form member to provide improved fluoroscopic or x-ray visualization of the wire-form member in the body while imparting sufficient elasticity to enable the wire-form member to elastically self-recover from its characteristic deformed configuration.

In various preferred embodiments, the wire-form metal member comprises a draw-form. The second metal is nitinol. The high density metal is tantalum. The wire-form member comprises the main body of a medical guidewire.

Description of the Preferred Embodiment(s)

We first briefly describe the drawings.

Drawings

Fig. 1 is a longitudinal cross-sectional view of a medical wire according to the invention; while Fig. 1a is a cross-sectional view taken along the lines aa in Fig. 1;

Fig. 2 is a schematic illustration of a wire according to the invention in a stressed, bent configuration;

Fig. 3 is a graph of load versus displacement for several wires according to the invention;

Fig. 4 is a view of a guidewire of the invention for introduction into a body lumen; while Fig. 4a a cross-sectional view along lines bb, Fig. 4b is a cross-sectional view along lines cc in Fig. 4; and Fig. 4c is a greatly enlarged cross-sectional view of portion d of Fig. 4;

Fig. 5 is a schematic of a blood clot filtration device of the invention for implantation in a blood vessel;

Fig. 6 is a schematic illustration of an ultrasonic wire device of the invention and Fig. 6a is longitudinal cross-sectional view of a portion of another embodiment of an ultrasonic device, having air-filled microspheres (shown greatly enlarged) at the interface of the core and outer member.

Description

Referring to Figs. 1 and 1a, a preferred embodiment of the invention is a medical wire 2 that includes a longitudinal outer member 4 with an axis 6. The longitudinal member 4 is formed of a metal having desirable properties, such as high elasticity and biocompatibility of its exposed outer surface 7. (The surface 7 may include a non-metal coating of, e.g., fluorocarbons, silicones, hydrophilic and lubricous biocompatible materials.) About the axis 6 is a core material 8 including a metal with a density greater than the longitudinal member 4 to enhance the radiopacity of the wire. The core 8 is bonded to and substantially enclosed by the outer member 4 such that it does not have any substantial exposed surface and therefore does not contact body tissue when positioned within the body during use.

As illustrated, preferably the core 8 is a continuous solid member in intimate contact and bonded with the outer member 4 without the formation of substantial voids in the interface 10 between the core and outer member. Preferably, the elastic properties of the wire 2 are dominated by the elastic properties of the longitudinal member 4. The core material 8 enhances the radiopacity of the wire 2 but preferably does not substantially effect the mechanical performance of the wire. In preferred embodiments, the cross-sectional dimension of the core (d_c) is less than about 70% (but typically greater than about 1% or 10%) of the outer

cross-sectional dimension (d_o) of the wire, more preferably between about 40% and 25%. The wire is especially useful in applications where the medical device must be sized small, such as for use in the vascular system, for example, as a guidewire tip which has an outer dimension (d_o) of less than about 0.015 inch, e.g., even less than 0.0075 inch and for which less dense metals are required for advantageous elastic properties. The invention is particularly useful for enhancing radiopacity of devices with dimensions of about 0.025 inch or less.

Referring to Fig. 2, the wire 2 is shown in a bent position, as it may be, for example when in use in a device positioned within the body. The inner and outer portions (i) and (o), experience a wide range of tension and compression as the wire is bent. An advantage of the invention, is that by positioning the core material 8 near the axis 6, the range of tension and compression imposed on the core is reduced and a wide latitude of dense, substantially radiopaque materials can be used which would otherwise might not be suitable for their response to bending or other mechanical properties.

The relative dimension of the core and outer member and the particular materials used for these elements are selected based on the desired over-all mechanical properties of the wire and the degree to which x-ray visibility is to be enhanced, since the core affects the mechanical properties of the wire compared to a solid wire formed of the outer material, and the radiopacity is a function of the sum of the mass between an x-ray beam source and detector. For example, large devices or devices with overlapping portions, may require less radiopaque material to provide sufficient visibility. Similarly, the location of use in the body may affect the amount of dense material needed for

sufficient visibility. The visibility of a device can be tested by known techniques such as ASTM Designation F640-79 "Standard Test Method for Radiopacity of Plastics for Medical Use". In this test, the background densities which may be encountered clinically are mimicked by an aluminum plate positioned over the wire having various thicknesses.

The properties of the outer member metal and core which may be considered include density, modulus of elasticity (in annealed and hardened states), biocompatability (primarily a factor for the material of the outer longitudinal member), flexural stiffness, durability, tensile and compression strength, acoustic impedance (as discussed in a further embodiment below) and the required radiopacity and resolution.

Preferably, for elastic members, the outer member is formed of a continuous solid mass of a highly elastic biocompatible metal such as a superelastic or pseudo-elastic metal alloy, for example, a nitinol (e.g., 55% nickel, 45% titanium). Other examples of superelastic materials include, e.g., Silver-Cadmium (Ag-Cd), Gold-Cadmium (Au-Cd), Gold-Copper-Zinc (Au-Cu-Zn), Copper-Aluminum-Nickel (Cu-Al-Ni), Copper-Gold-Zinc (Cu-Au-Zn), Copper-Zinc (Cu-Zn), Copper-Zinc-aluminum (Cu-Zn-Al), Copper-Zinc-Tin (Cu-Zn-Sn), Copper-Zinc-Xenon (Cu-Zn-Xe), Iron Beryllium (Fe_3Be), Iron Platinum (Fe_3Pt), Indium-Thallium (In-Tl), iron-manganese (Fe-Mn) Nickel-Titanium-Vanadium (Ni-Ti-V), Iron-Nickel-Titanium-Cobalt (Fe-Ni-Ti-Co) and Copper-Tin (Cu-Sn). See Schetsky, L. McDonald, "*Shape Memory Alloys*", Encyclopedia of Chemical Technology (3rd ed.), John Wiley & Sons, 1982, vol. 20. pp. 726-736 for a full discussion of superelastic alloys. Other examples of metals suitable for the outer member include stainless steel, titanium and various alloys of these metals and the precursor of superelastic alloys.

Precursors of superelastic alloys are those alloys which have the same chemical constituents as superelastic alloys, but have not been processed to impart the superelastic property. Such alloys are further described in co-owned and co-pending U.S. Serial No. 07/507,375, filed April 10, 1990, the entire contents of which is hereby incorporated by reference.

The core material is preferably a continuous solid mass, but may also be in a powder-form. The core includes a metal that is relatively dense to enhance radiopacity. Preferably, the core metal has a density of about 9.9 g/cc or greater. Most preferably, the core is formed of tantalum (density = 16.6 g/cc). Other preferred materials and their density include tungsten (19.3 g/cc), rhenium (21.2 g/cc), bismuth (9.9 g/cc), silver (16.49 g/cc), gold (19.3 g/cc), platinum (21.45 g/cc), and iridium (22.4 g/cc). In some cases barium can be used in the core. The core may be formed of alloys such as those including the above materials. Typically, the core is somewhat stiffer than the outer membrane. Preferably, the core metal has a low modulus of elasticity, e.g., preferably below about 550 GPa, e.g., such as tantalum (186 GPa). A smaller difference between the modulus of elasticity between the outer material and core, results in a smaller variation of the modulus from that of the outer material in the wire of the invention. For larger differences, a smaller core may be used so as to produce a wire in which the elastic properties are dominated by the outer material.

The outer member and core may be in many cross-sectional geometric configurations, such as circular, square, triangular, hexagonal, octagonal, trapezoidal and the geometrical configuration of the core may differ from that of the longitudinal member. For example, the wire may be rectangular in cross-section with a rectangular

core or triangular or hexagonal in cross-section with a circular core. The wire may also take on the form of tubing with a lumen within the core extending along the axis of the wire. The wire may also include successive layers of different metals to form a composite system. The core may extend intermittently along the axis in a desired pattern.

The medical device may be formed, for example, by drilling a relatively large rod of the outer member material to form a lumen, positioning a rod of core material in the lumen, sealing the ends of the lumen, e.g., by crimping and drawing as known in the art, through a series of dies of decreasing diameter until the desired outer diameter is achieved. The device may be heat treated to anneal, harden or impart superelastic properties. Other methods of formation may be, e.g., by coating the core with the desired outer material such as by electro- or electroless plating. The materials used in the outer member and core are also selected based on their workability for forming the wire, including factors such as machinability, for forming the longitudinal member into a tubular piece and the core member into a rod shaped piece, stability in gaseous environments at annealing temperatures, properties related to welding, drawing, forging, swaging, the ability to accept coatings such as adhesives, polymers, lubricants and practical aspects such as cost and availability.

Other examples follow.

Example 1

A 500 foot length of wire (0.0052 inch in diameter) having an outer member formed of a precursor of a nitinol (55% Ni/45% Ti) superelastic alloy and a core material of tantalum (0.00175 inch in diameter) is formed by drilling a 0.25 inch diameter bore in a 0.75 inch rod of the outer member material and providing in the drilled lumen a tantalum member of substantially matched outer diameter. The rod is mechanically forged in a standard hot forging and rolling apparatus, then hammered such that no substantial voids between the core and outer longitudinal member are present. One end of the rod is sealed and the opposite end is cold drawn longitudinally through a dye to the final diameter. Initially, the outer member of the wire is the precursor of a superelastic alloy, i.e., it has not been heat treated to impart the superelastic property.

Referring to Fig. 3, load versus displacement curves are illustrated. (For clarity, curves C, D and A are offset, successively, 0.025 inch on the x-axis.) Curve A illustrates the wire as discussed in the above paragraph prior to heat annealing which induces the superelastic property; the wire exhibits substantially linear elastic strain as a function of stress to a break point z. Curves B, C, D illustrate stress/strain curves after annealing the wire at 460°C for 3 minutes, 5 minutes and 15 minutes, respectively. As these curves illustrate, the superelastic nature of the wire is substantially preserved, as evidenced by the substantial plateaus (p) on the stress/strain curve, despite the presence of the tantalum core. Also as illustrated, the stress at which constant displacement occurs decreases with increasing annealing, as would be expected with a superelastic material. The mechanical properties of the

wire, therefore, are dominated by the nitinol alloy, despite the presence of the tantalum core.

Referring to Table I, the modulus of elasticity and plateau stress calculated based on stress-strain measurements as above, are compared for the wires of the invention and a solid wire of Ni-Ti alloy.

Table I

	Ni-Ti	Ta Cored Ni-Ti	% Change in Cored Wire
Diameter	.0038"	.0052"	--
Area	$1.134 \times 10^{-5} in^2$	$2.124 \times 10^{-5} in^2$	--
(Modulus of Elasticity)			
Precursor	5,401,300 psi	7,373,865 psi	+27%
460° @ 3 mins	6,967,150 psi	6,657,000 psi	-4.5%
460° @ 5 mins	5,381,160 psi	5,721,100 psi	+6.0%
460° @ 10 mins	5,139,310 psi	-------	--
460° @ 15 mins	5,143,960 psi	5,551,924	+7.4%
Plateau Stress (loading)			
460° @ 3 mins	101,400 psi	94,174	-7.2%
460° @ 5 mins	89,056 psi	84,757	-4.8%
460° @ 10 mins	79,357 psi	------	--
460° @ 15 mins	72,303 psi	75,339 psi	+4.1%

As the results in Table I illustrate, the modulus of elasticity of the wires of the invention was varied less than 30% compared to the solid Ni-Ti wire. The plateau stress of the wires of the invention using a superelastic outer member was varied less than about 10% compared to a solid Ni-Ti superelastic wire. The wire formed as described exhibits about 30% or more enhanced x-ray visibility over a wire of the same thickness formed of solid material. Preferably, wires as described, dominated by the mechanical properties of the outer superelastic member and exhibiting generally satisfactory radiopacity have outer diameter (d_o) of about 0.008 to 0.0045 inch with a core diameter (d_c) of about 0.0014 to 0.00195 inch.

Example 2

Referring now to Fig. 4, a guidewire is shown of the type introduced into the body lumen, e.g., a blood vessel for positioning, for example, a catheter or the like. The guidewire 60 includes a proximal body section 62 of constant diameter, a taper 64 and a distal end 66 of constant, smaller diameter than the body section 62. Referring to Fig. 4a, in the preferred embodiment, the outer diameter of the proximal end 62 is d_{po} about 0.038 inch and the diameter of the core is, d_{pc}, about 0.003 inch. Referring to Fig. 4b, at the distal end 66, the outer diameter is d_{do} about 0.005 to 0.008 inch and the core is d_{dc} about 0.003 inch. In the taper 64, only the outer member 4 tapers to reduced diameter, while the core remains of constant diameter. Such a wire might be formed by preparing a specimen of the outer material with an inner lumen, drawing the outer material to form the taper and reduced diameter distal portion, followed by positioning the core in the lumen. Alternatively, the structure of Figs. 4 *et seq.* could be formed from a wire of constant diameter outer member and core and removing portions of the outer member, e.g., by grinding, to leave a relatively lower ratio of outer member to core in the taper and distal end. Alternatively, the core may taper at the same position as the outer member tapers by drawing the wire to form the taper after positioning the core within the outer material. The radiopaque core preferably extends the length of the wire so that the entire wire can be imaged, allowing viewing of the length of a tortuous body lumen. The cored wire may also be used as the distal tip of a conventional wire. The guidewire may also include a coil spring, e.g., about the distal tapered region, and/or incorporate a polymer coating. As well as improving the radiopacity, the cored wire can be tailored to exhibit other advantageous

features, such as enhanced tensile strength by using a core material that has this property.

Example 3

Referring to Fig. 5, a wire of the invention may also be used in a blood clot filtration device of the type positioned within a blood vessel. The filtration device 50 includes a nose cone 52 downstream relative to blood flow 58 and a series of legs 54. The legs include hook members 102 which are embedded in the wall 56 of the body lumen to secure the filter therein. A filter of this type is further described in Herms U.S. 4,817,600 and El-Nou Nou U.S. 5,059,205, the entire contents of which are hereby incorporated by reference. The wires 54 are formed as described herein including a radiopaque core within an elastic longitudinal member. Preferably, the overall diameter of the wire is 0.035 to 0.037 with a core diameter of about 0.005 inch. The outer member is preferably nitinol, stainless steel or titanium and the core is tantalum. It will be understood that smaller diameter wires for smaller filtration device legs may also be used, in which case, a dense core is particularly useful for enhancing radiopacity.

Example 4

Referring now to Figs. 6 and 6a, an ultrasonic device 70 is shown to include a wire 72 including an inner core 74 and an outer member 76. The wire 72 extends from a proximal end 78, attached to an ultrasonic source mechanism 80, to a distal end 82 which is positioned at a location where ultrasonic energy is to be delivered. Briefly, the source 80 includes a clamping mechanism 86 to couple the core near the distal end 78 of the wire to a diaphragm 88 which is vibrated ultrasonically by a piston transducer 90. The transducer 90 includes a phosphorous-bronze bell 92 whose tension may be adjusted by screw member 94. The magnetic field

from coils 96 cause the transducer to vibrate when electrical energy is supplied through leads 98. Cooling vents 100 surround the coils 98. Ultrasonic energy supplied by the mechanism 80 to the core at the proximal portion 78 of the wire is transmitted through the core to the distal end 82 where it can be utilized to treat tissue. Referring to Fig. 6a, in some embodiments, the core 74 is bonded to the outer member 76 at intermittent points, leaving therebetween air-filled microspheres 102 which impede the transmission of ultrasonic energy laterally. The microspheres could be produced by machining grooves into the core or outer member before assembly.

By proper selection of the outer and core metals enhanced transmission of ultrasonic energy through the core may be achieved while minimizing lateral mode losses through the outer material. Preferably, the metals are selected based on their acoustic impedance (Z_1, Z_2) to induce internal reflection of acoustic waves propagating off axis. An advantage of the system is that lower power may be applied so that the transmission system operates at lower temperature. The outer member can further be selected to reduce vibration. A preferred embodiment of an elastic probe employs high acoustic transmitting titanium at the core and nitinol as the outer member. In another embodiment, the core member may be for example, nitinol and the outer member stainless steel. In another embodiment, the core is tantalum. The outer member could also be formed of a non-metal, e.g., carbon or glass. The ultrasound energy could be used to ablate tissue, enhance delivery of drugs and induce relaxation of tissue, e.g., tumors and in eye surgery e.g., to dissolve cataracts. The acoustic energy can be provided to the probe by axial excitation as illustrated above or by torsional excitation or a combination thereof.

Other Examples

The invention can be embodied in examples too numerous to mention, as will be understood by those skilled in the art. While the preferred embodiment described herein is in the form of a wire, it will be realized that medical components could be of various shapes and configurations including e.g., a radiopaque core and less dense outer member. In other embodiments, the outer member is substantially more radiopaque (e.g., tantalum) compared to the inner member (e.g., stainless steel), for example, for use in guidewire applications to provide a highly radiopaque wire with enhanced flexibility.

Other embodiments are in the following claims.

Claims

1. A medical device having at least a portion for use within the body, said portion comprising:

an extended metal outer member having an exposed outer surface, and

a core within said outer member comprising a metal different than the metal of said outer member,

said core being secured within and substantially enclosed by said outer member.

2. The medical device of claim 1 wherein said extended metal outer member is comprised of a metal of predetermined density and said core is comprised of a metal having a density substantially greater than said outer member to enhance radiopacity of said device.

3. The medical device of claim 2 where said portion is in the form of a medical wire, wherein said metal outer member is a longitudinal member and said radiopaque core is positioned along the axis of said longitudinal member.

4. The medical device of claim 3 wherein said radiopaque core has a density of about 9.9 g/cc or greater.

5. The medical device of claim 4 wherein said core is selected from the group consisting of tungsten, tantalum, rhenium, iridium, silver, gold, bismuth, platinum and alloys thereof.

6. The medical device of claim 4 wherein said core has a modulus of elasticity of about 550 GPa or less.

7. The medical device of claim 6 wherein said core has a modulus of elasticity of about 200 GPa or less.

8. The medical device of claim 3 wherein said outer member is selected from the group consisting of superelastic alloys, precursor alloys of superelastic alloys, stainless steel, and titanium and its alloys.

9. The medical device of claim 8 wherein said superelastical alloy is nitinol.

10. The medical device of claim 1 or 3 wherein the core is about 1 to 40% of the cross-sectional dimension of said component.

11. The medical device of claim 10 wherein the core is about 25% or more of said cross-sectional dimension of said component.

12. The medical device of claim 11 wherein the core is about 28% or less of the cross-sectional dimension of said component.

13. The medical device of claim 1 or 3 wherein the cross-sectional dimension of said component is less than about 0.025 inch.

14. The medical device of claim 13 wherein said outer member has a cross-section of about 0.0045 to 0.008 inch and said core member has a cross section of about 0.0014 to 0.00195 inch inner diameter.

15. The medical device of claim 1 or 3 wherein said core is a solid metallic member.

16. The medical device of claim 3 wherein said outer member has portions of varying dimension.

17. The medical device of claim 16 wherein said outer member has a taper portion.

18. The medical device of claim 17 wherein said core has a constant inner dimension in portions corresponding to said varying outer dimension of said outer member.

19. The medical device of claim 1 or 3 wherein said portion is in the form of a medical guidewire.

20. The medical component of claim 1 or 3 wherein said portion is in the form of elastic leg members of a vascular filter.

21. The medical device of claim 1 or 3 wherein said outer member and core are of circular cross-sectional configuration.

22. The medical device of claim 1 wherein said portion is in the form of an ultrasonic probe.

23. The medical device of claim 22 wherein said probe is an elastic probe having a titanium core and nitinol outer member.

24. The medical device of claim 22 wherein said probe and core are constructed of materials of substantially different acoustic impedance.

25. The medical device of claim 22 wherein acoustic energy is provided by axial excitation.

26. A medical wire device having at least a portion for use within the body, said portion further comprising:

an extended longitudinal metal outer member having a predetermined density and an exposed outer surface, and

a continuous solid core positioned along the axis of said outer member including a metal having a density of about 9.9 g/cc or greater and greater than the density of said outer member for enhancing radiopacity of said wire,

said core being secured within, and substantially enclosed by said outer member and being about 10 to 50% of the cross-sectional dimension of said portion for use within the body.

27. The device of claim 26 wherein the core material is tantalum.

28. The device of claim 27 wherein the outer material is nitinol.

29. The device of claim 26 or 27 wherein the cross sectional dimension of said portion is about 0.025 inch or less.

30. The device of claim 29 wherein said outer member has a cross-section of about 0.0045 to 0.008 inch and said core member has a cross section of about 0.0014 to 0.00195 inch inner diameter.

31. The device of claim 26 or 28 wherein said wire is in the form of a guidewire.

32. The medical device of claim 31 wherein said outer member has portions of varying dimension.

33. The medical device of claim 32 wherein said outer member has a taper portion.

34. The medical device of claim 33 wherein said core has a constant inner dimension in portions corresponding to said varying outer dimension of said outer member.

35. The device of claim 34 wherein the cross sectional dimension of said portion is about 0.035 to 0.037 inch.

36. The device of claim 35 wherein said core is about 0.005 inch in diameter.

37. The medical component of claim 26 or 28 wherein said portion is in the form of elastic leg members of a vascular filter.

38. A method for medical treatment comprising:

providing a medical device for performing a desired treatment,

incorporating on at least a portion of said device a radiopaque medical component, comprising

an extended metal outer member having a predetermined density and exposed outer surface,

a core including a metal having a density substantially greater than said outer member to enhance radiopacity,

said core being secured within and substantially enclosed by said outer member, and

introducing said portion including said radiopaque medical component into the body, and

observing said medical component by x-ray fluoroscopy.

39. The method of claim 38 wherein said medical device is a guidewire and said medical component is a portion of said guidewire, said method further including steering said guidewire through the body from the proximal end.

40. The method of claim 38 wherein said medical device is a vascular filter.

41. A medical device capable of placement or manipulation in the body by means external of the body under guidance of a fluoroscope, said device comprised at least in part of an elongated wire-form metal member adapted to be subjected to elastic deformation to enable the device to be forced into a characteristic deformed configuration during a stage of use and to elastically self-recover from said deformation when deformation forces are relieved, said wire-form metal member comprised of a core of a first metal of a first selected thickness and an intimately surrounding sheath of a second selected metal of a second thickness, said first metal being a high density metal that demonstrates characteristic relatively high radiopacity and said second metal being a lower density metal having substantially more elasticity than said first metal, the combined effect of the selected thicknesses of said first and second metals in said wire-form member serving to enhance the radio-opacity of said wire-form member to provide improved fluoroscopic or x-ray visualization of said wire-form member in the body while imparting

sufficient elasticity to enable the wire-form member to elastically self-recover from its characteristic deformed configuration.

42. The medical device of claim 41 wherein said wire-form metal member comprises a draw-form.

43. The medical device of claim 42 wherein said second metal is nitinol.

44. The medical device of claim 43 wherein said high density metal is tantalum.

45. The medical device of claim 41, 42, 43 or 44 wherein said wire-form member comprises the main body of a medical guidewire.

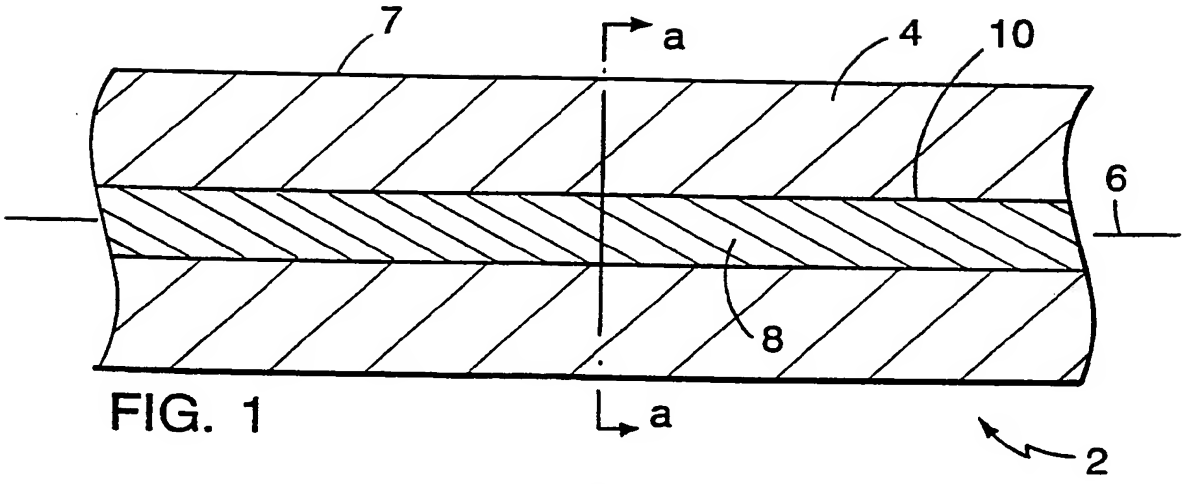


FIG. 1

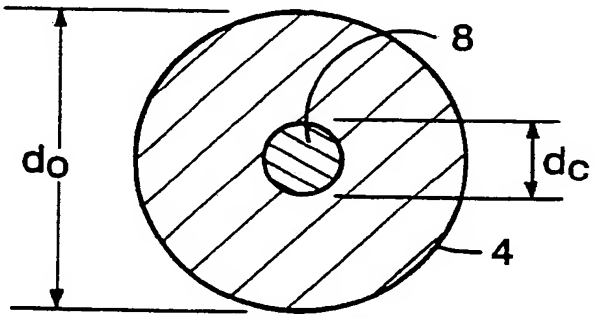


FIG. 1a

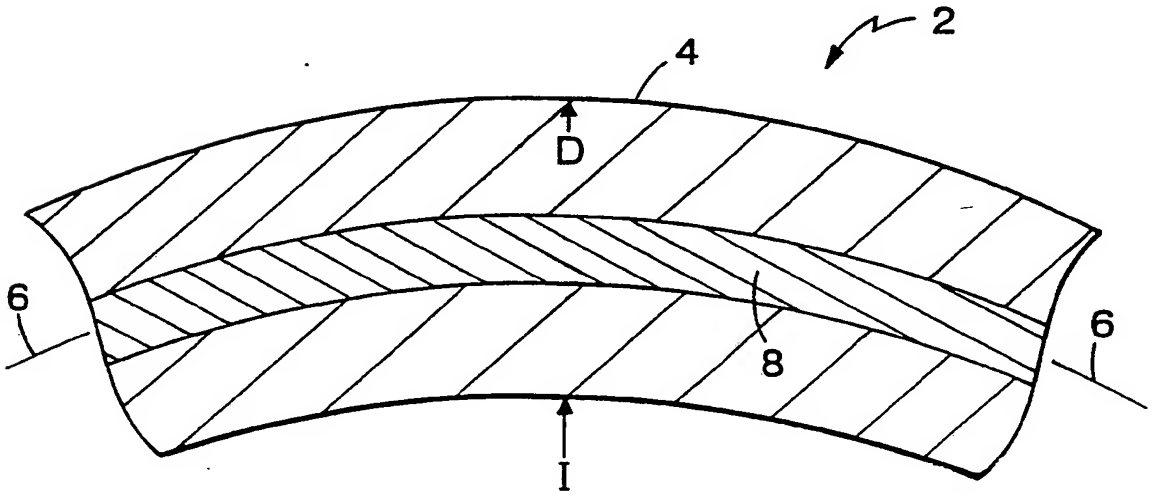
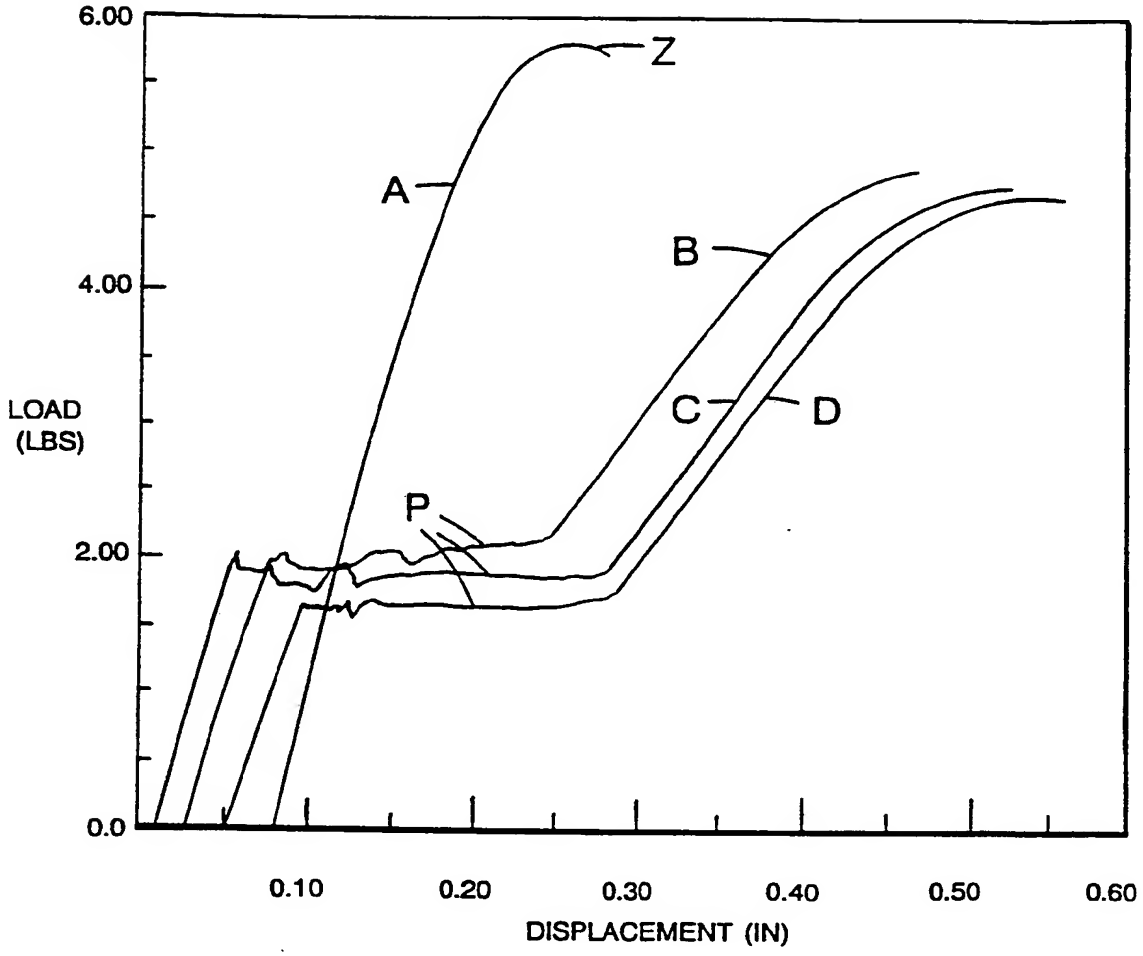


FIG. 2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(LBS)
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A
B
C
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DISPLACEMENT (IN)

FIG. 3

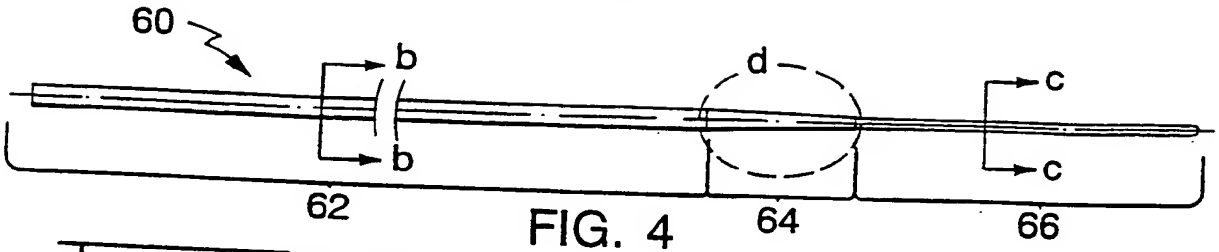

FIG. 4

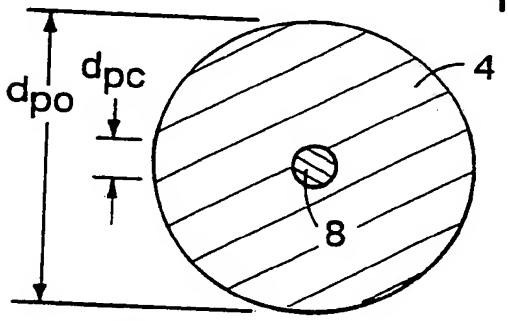

FIG. 4a

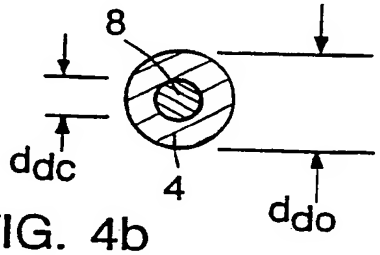

FIG. 4b

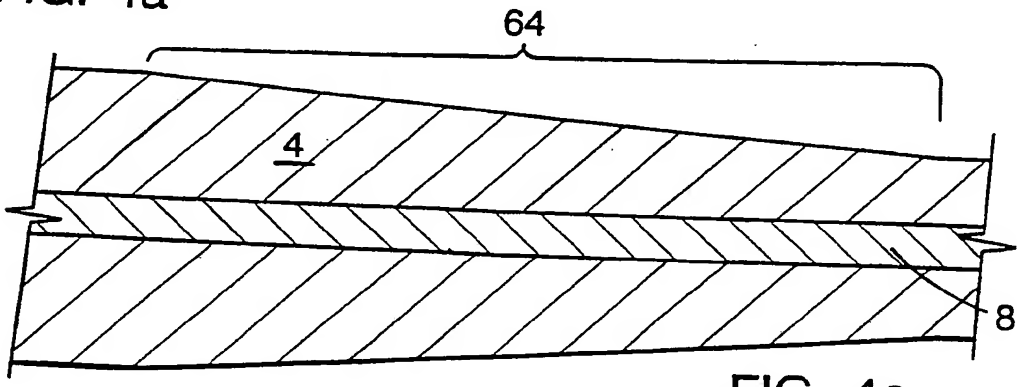

FIG. 4c

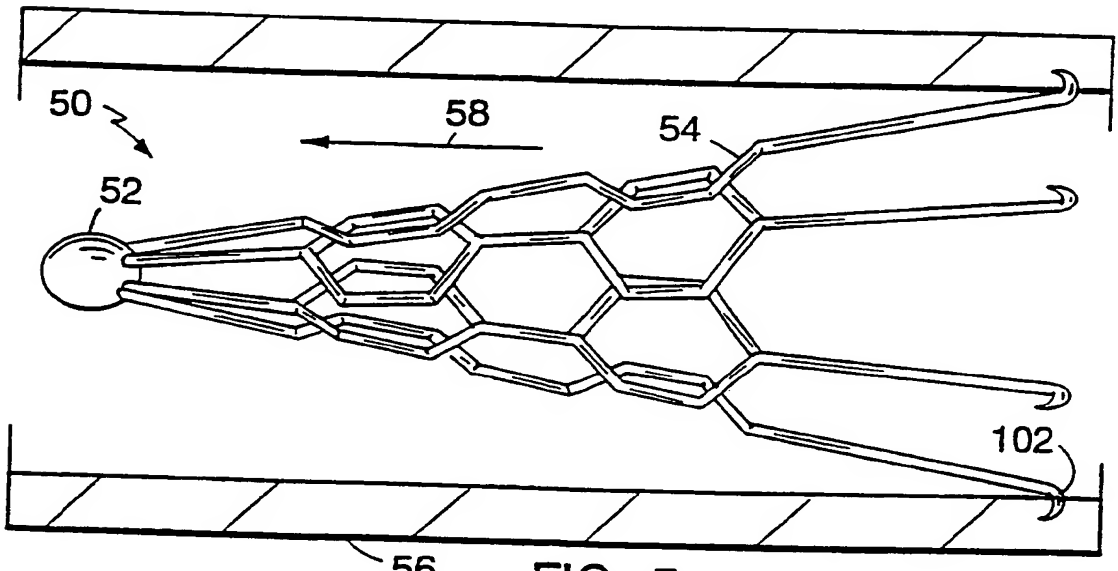

FIG. 5

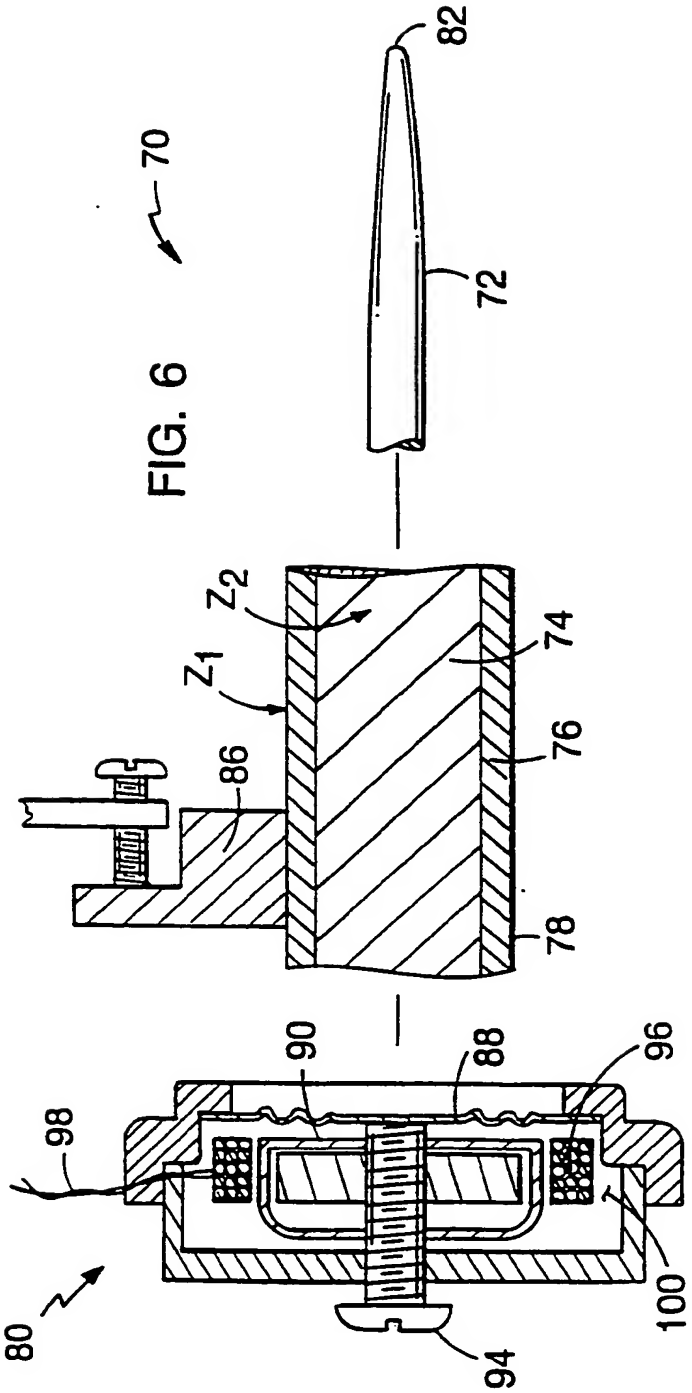

FIG. 6

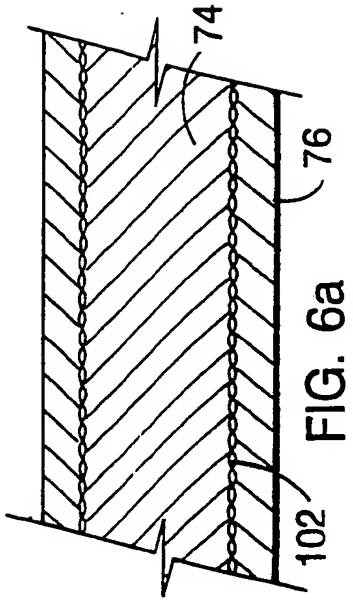

FIG. 6a

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US93/02871

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61M 29/02; A61F 2/04; A61B 5/00
US CL :128/772; 623/1, 11; 606/194, 195
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/772; 623/1, 11; 606/194, 195; 623/12; 428/386; 389, 397, 364, 375, 378, 379

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y A	US, A, 4,950,227 (SAVIN ET AL.) 21 August 1990. See column 5, lines 40-64; column 4, lines 9-16; figures 1 and 2; column 6, lines 19-20.	1-22, 25, 26, 38-42 23, 24, 27-37, 43-45
Y A	US, A, 5,069,226 (YAMAUCHI ET AL.) 03 December 1991. See column 8, lines 1-54 and column 2, lines 50-56, column 5, line 17 - column 6, line 36; figure 1.	1-22, 25, 26, 38-42 23, 24, 27-37, 43-45

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 07 JUNE 1993	Date of mailing of the international search report JUL 13 1993
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. NOT APPLICABLE	Authorized officer DEBRA S. BRITTINGHAM Telephone No. (703) 308-3401

Form PCT/ISA/210 (second sheet)(July 1992)*